

Identifying Gaps in Real-World Management of Diabetes in Nigeria: A Subset Analysis of Cross-Sectional Wave-7 Data from the International Diabetes Management Practices Study

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Abstract

Background/Purpose: Poor glycemic control in Nigeria necessitates assessment and standardization of diabetes care. This study aimed to assess real-world management of people with type 2 diabetes mellitus (T2DM) and type 1 diabetes mellitus (T1DM) in Nigeria. **Methods:** This cross-sectional phase of the seventh wave of International Diabetes Management Practices Study, conducted between 22nd August and 30th September 2016, included adults with T1DM or T2DM during a two-week recruitment period. **Results:** Of 304 people with T2DM, 187 received oral glucose lowering drugs (OGLDs) only; 88 received OGLDs + insulin; 27 received insulin only. Metformin + sulfonylureas (128/187; 68.45%) and premix only (76/115; 66.09%) were the most used OGLD and insulin regimens respectively. Of 77 people with T1DM, all received insulin; six (7.79%) received OGLDs. Insulin initiation was noted around five years after diabetes diagnosis in T2DM (diabetes duration: 8.69 + 7.16 years; duration of insulin treatment: 3.17 ± 4.49 years). Proportion of people achieving glycemic targets (HbA1c < 7%: T2DM [66/202, 32.67%], T1DM [6/56, 10.71%]; clinical targets: T2DM [28/112, 25.00%], T1DM [14/74, 18.92%]; triple targets: T2DM [7/286, 2.45%], T1DM [3/64, 4.69%]) was low. Cost of medications/strips (92/144; 63.89%) and lack of experience in self-managing insulin (46/144; 31.94%) were main reasons for non-achievement of glycemic targets. Diabetes complications (253/372; 68.01%), hypoglycemia (symptomatic in the preceding three months: total = 97/373

[26.01%], T2DM = 61/300 [20.33%], T1DM = 36/73 [49.32%]; severe in the preceding 12 months: total = 32/368 [8.70%], T2DM = 17/298 [5.70%], T1DM = 15/70 [21.43%]) and hospitalizations (90/369; 24.39%) were common. Most participants (T2DM: 216/304 [71.05%]; T1DM: 62/76 [81.58%]) had a glucometer at home; few (T2DM: 44/113 [38.94%]; T1DM: 38/73 [52.05%]) self-managed both blood glucose and insulin. **Conclusion:** Early insulinization and subsidized healthcare can improve long-term diabetes outcomes in Nigeria.

Keywords

Diabetes, Management Gaps, Nigeria

1. Introduction

Diabetes mellitus (DM), characterized by chronic hyperglycemia, resulting from abnormalities in physiological functioning of insulin, is rapidly becoming one of the most common non-communicable disease worldwide [1] [2] [3] [4] [5]. International Diabetes Federation (IDF) estimates indicate that globally, around 463 million people were living with diabetes and the prevalence is estimated to rise to 700 million in 2045 [6] [7] [8]. In Africa, the prevalence of diabetes has increased from 4 million to 25 million between 1980 and 2014 [5]. The major factors contributing to the rapid increase of DM in urban Africa are changing demographic trends, increased rate of urbanization, unhealthy diets, and gradual adoption of Western lifestyles. The prevalence rate of DM in urban Africa is equal to, or even higher than those reported in developed countries [9] [10]. Due to rapid urbanization, Nigeria has the highest burden of diabetes in Africa [2] [10], accounting for 3.9 million diabetes cases and 105,091 diabetes-related deaths in 2013 which is estimated to increase annually by 125,000 between 2010 and 2030 [8] [9] [11] [12].

In the Nigerian population, 62% of people with diabetes had poor glycemic control, therefore, leading to a high incidence of diabetes complications [13]. People in Nigeria who have diabetes, experience a higher prevalence of microvascular than macrovascular complications due to factors such as co-existent hypertension, late presentation and diagnosis, poor access to essential antidiabetic drugs and services, poor diabetes management, and the consequential poor glycemic control [14] [15] [16].

The American Diabetes Association/European Association of Study in Diabetes (ADA/EASD) guidelines recommend meeting glycemic goals to reduce both onset and progression of microvascular complications [17]. These guidelines have also outlined several recommendations including early insulinization, continuing medical care and patient self-management education to promote achievement of optimal glycemic control [17]. Consequently, there has been increasing focus internationally on developing an “individualized treatment approach” and

adoption of country-specific guidelines to optimize treatment outcomes [18].

In Nigeria, a large-scale collaboration is required among healthcare providers, pharmaceutical industries, policymakers and National Agency for Food and Drug Administration and Control not only to achieve optimal glycemic control in people with DM, but also to promote adequate diabetes management practices governed by appropriate regulations. Currently, two national governing bodies, namely, the Diabetes Association of Nigeria and the Endocrine and Metabolism Society of Nigeria are responsible for framing diabetes management guidelines by collaborating with policymakers and non-governmental bodies. At present, there is also a national guideline document on diabetes and a Lagos State Guideline, sponsored by Structured Healthcare Initiatives [2].

Despite these guidelines, several research questions and real-world practice gaps in diabetes management remain unanswered in Nigeria, necessitating the conduct of nation-wide programs for assessment and standardization of diabetes care towards advancing diabetes awareness and empowerment of healthcare professionals in rural/urban areas [2] [19]. However, limited data is available on real-world diabetes management practices to support such policy and programming in Nigeria [4] [11] [20]. Therefore, this study was conducted to assess the real-world management practices of people with type 2 DM (T2DM) and type 1 DM (T1DM) in Nigeria.

2. Methods

The International Diabetes Management Practices Study (IDMPS) is an ongoing multicenter, cross-sectional and/or longitudinal observational study with yearly surveys, also designated as waves. The cross-sectional phase consists of 2-week duration. The first wave of IDMPS study was initiated in 2005 and the current study is part of the seventh wave (2016).

This study was conducted in Nigeria between 22nd August 2016 and 30th September 2016, in accordance with the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) [21] and all applicable amendments and in compliance with the guidelines for Good Epidemiology Practice. Each participating site completed the essential local regulatory compliance activities (e.g., Institutional Review Board [IRB]/Independent Ethics Committee [IEC]) including the local data protection act. The study design and reporting format were in accordance with recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. All participants signed written informed consent before entering the study.

Investigator selection

Physicians were selected randomly from a stratified sample with the criteria of having experience in managing people with diabetes and prescribing insulin therapy (initiation and titration). The number of participating investigator(s) and their profiles were determined based on each country and the study sample size (the number of participants was divided by 10 and rounded off to the next

digit). In Nigeria, 33 physicians were planned to be selected.

Participant selection

Each physician enrolled the first ten adults with T2DM and the first five adults with T1DM satisfying the eligibility criteria.

Eligibility criteria

Adults with T1DM or T2DM, with complete data regarding treatment of diabetes, visiting physicians during the two-week recruitment period were included. Those participating in another clinical trial, taking temporary insulin treatment, or those who had participated in a previous wave of IDMPs were excluded.

Statistical analysis

Sample size calculation

The sample size was determined on a country basis, using the following formula:

$$n = p (1 - p) \times (\varepsilon_a / e)^2$$

where “ n ” represents the per country sample size, “ p ” represents the estimated proportion of insulin-treated T2DM peoples, $\varepsilon_a = 1.96$ for $\alpha = 5\%$, e the absolute precision ($20\% \times p =$ the relative precision).

For Nigeria, based on the assumption that insulin was the least prescribed therapy in terms of proportions, the sample size was determined in order to establish the frequency of insulin-treated patients. A sample size of 396 participants was required based on the estimate to give an estimation of proportions with an absolute precision of 20% and a confidence interval of 95%.

Patient demography and baseline characteristics

Participating physicians recorded all baseline data for the evaluable population that was later transcribed onto the case report form. No safety data was collected in this study. However, based on country regulations, spontaneous adverse events were to be reported.

Statistical methods

Descriptive analyses were used on the recorded data. Qualitative data were summarized using number of non-missing data, number of missing data, counts and percentages (two-sided Confidence Interval (CI) 95% of proportion if pertinent), and quantitative data were summarized using quantitative descriptive statistics (number of non-missing data, number of missing data, mean, standard deviation, median, first and third quartiles, minimum and maximum). Missing data were not counted in the percentages. Statistical analyses were conducted with the SAS Software version 9.2.

3. Results

Investigator selection

Out of 31 physicians included, 22 were specialists (endocrinologists or diabetologists) and 9 were non-specialists (general practitioners, primary care practitioners,

and internists/cardiologists). Most physicians (20/31, 64.5%) in the study practiced in public hospitals. The mean number of patients included by each physician was 12.42 ± 1.86 . Physicians had mean age of 44.87 ± 6.62 years and 48.38% (15/31) were men. On an average, endocrinologists or diabetologists had 17.82 ± 7.85 years of experience and usually saw 31 patients/day, while non-specialists had 18.56 ± 7.88 years of experience and usually saw 49 patients/day.

Most physicians (30/31; 96.77%) declared that they follow clinical practice guidelines, of which majority (22/30; 73.33%) followed IDF guidelines.

Participant disposition

Overall, 381 (77 people with T1DM and 304 people with T2DM) out of 385 recruited participants met the eligibility criteria and were included in the study.

Demographics and clinical characteristics

Mean age of participants was 51.55 ± 15.48 years (T1DM: 30.56 ± 11.58 years; T2DM: 56.86 ± 11.25 years). Nearly half (174/381; 45.67%) were men (T1DM: 36/77 [46.75%]; T2DM: 138/304 [45.39%]). Majority lived in urban areas (261/381; 68.50%) and had received university or higher education (204/381; 53.54%). Irrespective of the diabetes phenotype, majority of the participants did not have health insurance (**Table 1**).

Real-world practices and management of diabetes in Nigeria

Treatment patterns

About half (T1DM: 38/77 [50.00%]; T2DM: 153/304 [51.00%]; Total: 191/381 [50.80%]) of the participants followed a healthy diet and exercise plan (**Table 2**).

Among 304 people with T2DM, 187 were prescribed with oral glucose lowering drugs (OGLDs) only (of which more than half received metformin + sulfonylureas [128/187; 68.45%]), 88 with OGLDs + insulin, and 27 with insulin only. Among 77 people with T1DM, all were on insulin; only six (7.79%) were on an OGLD in addition to insulin (**Table 2**). Premixed insulin only was the most used insulin regimen (T2DM: 76/115 [66.09%]; T1DM: 56/77 [72.72%]) (**Table 2**).

Treatment adherence

Among the participants with T1DM, 39.20% (29/74) has discontinued insulin therapy. About one-third (38/113; 33.63%) of the people with T2DM had discontinued insulin. The mean duration of treatment prior to discontinuation of insulin therapy was 1.84 ± 1.67 months in the T1DM group and 4.18 ± 6.35 months in the T2DM group.

Delayed insulin initiation

In participants with T2DM, insulin treatment was initiated about 5 years after diagnosis of diabetes (diabetes duration: 8.69 ± 7.16 years; duration of insulin treatment: 3.17 ± 4.49 years). In participants with T2DM who received only insulin, treatment initiation started about a decade after diagnosis of diabetes (diabetes duration: 15.57 ± 9.38 years; duration of insulin treatment: 5.59 ± 6.42 years). In contrast, those participants with T2DM receiving insulin + OGLDs, insulin was initiated about seven years after diagnosis of diabetes (diabetes duration: 9.86 ± 6.93 years; duration of insulin treatment: 2.43 ± 3.42 years) (**Table 2** and **Table 3**).

Table 1. Baseline characteristics.

	T2DM					Total N = 304	Total N = 381
	T1DM N = 77	Diet and exercise N = 2	OGLD treatment N = 187	Insulin treatment N = 27	OGLD treatment + Insulin treatment N = 88		
Age (years)							
Mean (SD)	30.56 (11.58)	50.00 (14.14)	57.45 (11.78)	54.78 (10.39)	56.40 (10.32)	56.86 (11.25)	51.55 (15.48)
Median (Min-Max)	27.00 (19 - 75)	50.00 (40 - 60)	57.00 (25 - 86)	55.00 (32 - 79)	57.00 (38 - 78)	57.00 (25 - 86)	53.00 (19 - 86)
Gender							
Male	36 (46.75)	2 (100.00)	80 (42.78)	12 (44.44)	44 (50.00)	138 (45.39)	174 (45.67)
Female	41 (53.25)	0 (0.00)	107 (57.22)	15 (55.56)	44 (50.00)	166 (54.61)	207 (54.33)
Living Area							
Urban Area	53 (68.83)	1 (50.00)	125 (66.84)	21 (77.78)	61 (69.32)	208 (68.42)	261 (68.50)
Rural Area	2 (2.60)	0 (0.00)	15 (8.02)	0 (0.00)	6 (6.82)	21 (6.91)	23 (6.04)
Sub-Urban Area	22 (28.57)	1 (50.00)	47 (25.13)	6 (22.22)	21 (23.86)	75 (24.67)	97 (25.46)
Education Level							
Illiterate	1 (1.30)	0 (0.00)	15 (8.02)	0 (0.00)	3 (3.41)	18 (5.92)	19 (4.99)
Primary	4 (5.19)	0 (0.00)	32 (17.11)	3 (11.11)	16 (18.18)	51 (16.78)	55 (14.44)
Secondary	28 (36.36)	0 (0.00)	44 (23.53)	9 (33.33)	22 (25.00)	75 (24.67)	103 (27.03)
University/Higher Education	44 (57.14)	2 (100.00)	96 (51.34)	15 (55.56)	47 (53.41)	160 (52.63)	204 (53.54)
Health Insurance	13 (16.88)	1 (50.00)	62 (34.25)	6 (22.22)	33 (37.50)	102 (34.23)	115 (30.67)
Weight (kg); mean (SD)	61.99 (14.83)	86.00 (14.14)	77.30 (13.39)	79.71 (18.37)	78.00 (14.74)	77.77 (14.25)	74.58 (15.69)
Waist circumference (cm); Mean (SD)	79.09 (12.31)	100.00 (1.41)	97.92 (12.60)	98.15 (16.45)	97.23 (12.99)	97.75 (13.01)	93.98 (14.89)
BMI (kg/m ²); mean (SD)	22.72 (5.41)	26.60 (1.27)	28.48 (4.67)	29.72 (6.14)	28.24 (5.44)	28.51 (5.03)	27.34 (5.61)
Smokers	0 (0.00)	0 (0.00)	2 (1.07)	0 (0.00)	1 (1.14)	3 (0.99)	3 (0.79)
Past smokers	5 (6.49)	0 (0.00)	22 (11.76)	6 (22.22)	13 (14.77)	41 (13.49)	46 (12.07)
Hypertension*	14 (18.18)	0 (0.00)	139 (74.33)	15 (55.56)	66 (75.00)	220 (72.37)	234 (61.42)
SBP (mmHg); mean (SD)	116.01 (15.54)	131.50 (2.12)	133.68 (17.06)	135.85 (21.69)	135.92 (19.34)	134.51 (18.10)	130.77 (19.10)
DBP (mmHg); mean (SD)	73.30 (10.68)	84.50 (7.78)	80.84 (11.31)	79.63 (11.83)	80.89 (10.50)	80.77 (11.07)	79.26 (11.38)
Dyslipidemia*	16 (27.11)	1 (50.00)	95 (59.74)	16 (69.56)	57 (75.00)	169 (65.00)	185 (57.99)
Total cholesterol (mg/dl); Mean (SD)	170.91 (44.63)	219.00 (8.20)	176.43 (49.03)	179.11 (39.03)	180.36 (38.65)	178.27 (45.00)	177.18 (44.93)
LDL cholesterol (mg/dl); Mean (SD)	96.54 (39.86)	149.20 (30.12)	109.09 (43.79)	112.72 (31.41)	112.79 (31.69)	110.97 (39.39)	108.83 (39.70)
HDL cholesterol (mg/dl); mean (SD)	51.67 (13.86)	44.55 (19.16)	48.14 (18.82)	50.01 (15.80)	46.71 (14.19)	47.88 (17.20)	48.41 (16.79)

Continued

Serum Triglycerides (mg/dl); mean (SD)	93.85 (30.64)	118.45 (18.60)	104.66 (36.36)	90.11 (38.63)	86.78 (34.16)	98.17 (36.67)	97.59 (35.88)
Serum Creatinine (mg/dl); mean (SD)	1.19 (0.89)	1.10 (0.00)	1.29 (1.55)	1.24 (0.52)	0.97 (0.29)	1.19 (1.21)	1.19 (1.15)

All variables represent n (%) other than those specified. *Patient diagnosed with dyslipidemia if the patient has been diagnosed with hypercholesterolemia and/or any other form of dyslipidemia. Abbreviations: T1DM: type 1 Diabetes Mellitus; T2DM: type 2 Diabetes Mellitus; OGLDs: oral glucose lowering drugs; SD: standard deviation; min: minimum; max: maximum; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; LDL: low-density lipoprotein; HDL: high-density lipoprotein.

Table 2. Therapeutic management.

	T2DM						Total N = 381
	T1DM N = 77	Diet and exercise N = 2	OGLD treatment N = 187	Insulin treatment N = 27	OGLD + Insulin treatment N = 88	Total N = 304	
People who follow a healthy diet and exercise plan	38 (50.00)	2 (100.00)	94 (51.09)	13 (48.15)	44 (50.57)	153 (51.00)	191 (50.80)
No. of people receiving OGLD	6 (7.79)	-	187 (100.00)	-	88 (100.00)	275 (100.00)	281 (79.83)
No. of OGLDs							
0	71 (92.21)	-	0 (0.00)	-	0 (0.00)	0 (0.00)	71 (20.17)
1	6 (7.79)	-	40 (21.39)	-	61 (69.32)	101 (36.73)	107 (30.40)
Duration (months)	16.00 (16.06)	-	39.18 (46.08)	-	74.88 (75.02)	60.74 (67.18)	58.23 (66.15)
2	0 (0.00)	-	124 (66.31)	-	25 (28.41)	149 (54.18)	149 (42.33)
Duration (months)	-	-	45.96 (49.19)	-	76.17 (80.13)	51.03 (56.39)	51.03 (56.39)
>2	0 (0.00)	-	23 (12.30)	-	2 (2.27)	25 (9.09)	25 (7.10)
Duration (months)	-	-	24.87 (26.27)	-	30.50 (41.72)	25.32 (26.60)	25.32 (26.60)
Class of OGLDs							
Metformin only	6 (7.79)	-	40 (21.39)	-	58 (65.91)	98 (35.64)	104 (29.55)
Sulfonylureas only	0 (0.00)	-	0 (0.00)	-	2 (2.27)	2 (0.73)	2 (0.57)
Metformin + sulfonylureas	0 (0.00)	-	128 (68.45)	-	13 (14.77)	141 (51.27)	141 (40.06)
Other	0 (0.00)	-	19 (10.16)	-	15 (17.05)	34 (12.36)	34 (9.66)
No. of people receiving insulin	77 (100.00)	-	-	27 (100.00)	88 (100.00)	115 (100.00)	192 (100.00)
Duration of insulin treatment (years)	7.49 (8.86)	-	-	5.59 (6.42)	2.43 (3.42)	3.17 (4.49)	4.90 (6.91)
Basal only							
n	1	-	-	0	31	31	32
No. of injections	1.00 (0.00)	-	-	-	1.03 (0.18)	1.03 (0.18)	1.03 (0.18)
Total daily dose (IU)	10.00 (0.00)	-	-	-	16.90 (7.50)	16.90 (7.50)	16.69 (7.48)
Total daily dose (IU/kg)	0.24 (0.00)	-	-	-	0.21 (0.09)	0.21 (0.09)	0.21 (0.09)

Continued**Prandial only**

n	5			1	3	4	9
No. of injections	3.00 (0.00)	-	-	2.00 (0.00)	3.00 (0.00)	2.75 (0.50)	2.89 (0.33)
Total daily dose (IU)	62.40 (10.43)	-	-	22.00 (0.00)	38.00 (19.29)	34.00 (17.66)	49.78 (19.89)
Total daily dose (IU/kg)	1.24 (0.25)	-	-	0.31 (0.00)	0.48 (0.25)	0.43 (0.22)	0.88 (0.48)

Basal + prandial

n	12			0	1	1	13
No. of basal injections	1.08 (0.29)	-	-	-	1.00 (0.00)	1.00 (0.00)	1.08 (0.28)
No. of prandial injections	2.75 (0.62)	-	-	-	3.00 (0.00)	3.00 (0.00)	2.77 (0.60)
Total daily dose (IU)	40.33 (17.12)	-	-	-	54.00 (0.00)	54.00 (0.00)	41.38 (16.82)
Total daily dose (IU/kg)	0.74 (0.35)	-	-	-	0.57 (0.00)	0.57(0.00)	0.73 (0.34)

Basal + premix

n	3			0	3	3	6
No. of basal injections	1.00 (0.00)	-	-	-	1.00 (0.00)	1.00 (0.00)	1.00 (0.00)
No. of premix injections	2.00 (0.00)	-	-	-	2.00 (0.00)	2.00 (0.00)	2.00 (0.00)
Total daily dose (IU)	47.33 (6.43)	-	-	-	42.00 (0.00)	42.00 (0.00)	44.67 (5.01)
Total daily dose (IU/kg)	0.74 (0.12)	-	-	-	0.52 (0.05)	0.52 (0.05)	0.63 (0.14)

Premix only

n	56			26	50	76	132
No. of injections	2.06 (0.23)	-	-	2.00 (0.00)	1.94 (0.24)	1.96 (0.20)	2.00 (0.22)
Total daily dose (IU)	44.63 (16.99)	-	-	41.50 (16.06)	36.24 (16.49)	38.04 (16.43)	40.78 (16.92)
Total daily dose (IU/kg)	0.72 (0.28)	-	-	0.54 (0.21)	0.49 (0.25)	0.51 (0.23)	0.59 (0.27)

Devices used by the patient*[†]

Reusable pen	25 (32.47)	-	-	8 (29.63)	14 (15.91)	22 (19.13)	47 (24.48)
Disposable pen	24 (31.17)	-	-	9 (33.33)	44 (50.00)	53 (46.09)	77 (40.10)
Vials	35 (45.45)	-	-	11 (40.74)	31 (35.23)	42 (36.52)	77 (40.10)
Pump	0 (0.00)	-	-	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

All variables represent n (%) other than those specified. *A patient could receive more than one type of basal/prandial/premix insulin. [†]A patient could use more than one device. Abbreviations: T1DM: type 1 Diabetes Mellitus; T2DM: type 2 Diabetes Mellitus; OGLDs: oral glucose lowering drugs; IU: international units.

Sub-optimal glycaemic control

About one-tenth (6/56; 10.71%) of participants with T1DM and a third (66/202; 32.67%) of participants with T2DM had reached glycaemic target of HbA1c < 7% as per international guidelines (**Table 4**).

Physician-targeted glycaemic goals were reached in approximately one-fifth of insulin-treated participants (Total: 42/186, 22.58%; T1DM: 14/74, 18.92%; T2DM: 28/112, 25.00%). Less than a tenth (5/56; 8.93%) of participants with T1DM and

Table 3. Diabetes medical history

	T1DM N = 77	T2DM				Total N = 304	Total N = 381
		Diet and exercise N = 2	OGLD treatment N = 187	Insulin treatment N = 27	OGLD + Insulin treatment N = 88		
Duration of diabetes (years)	7.70 (8.76)	6.00 (7.07)	7.17 (6.21)	15.57 (9.38)	9.86 (6.93)	8.69 (7.16)	8.49 (7.51)
≤1	21 (27.27)	1 (50.00)	38 (20.43)	1 (3.70)	6 (6.82)	46 (15.18)	67 (17.63)
>1 ≤ 5	19 (24.68)	0 (0.00)	56 (30.11)	3 (11.11)	24 (27.27)	83 (27.39)	102 (26.84)
>5 ≤10	20 (25.97)	0 (0.00)	44 (23.66)	7 (25.93)	24 (27.27)	75 (24.75)	95 (25.00)
>10 ≤20	10 (12.99)	1 (50.00)	42 (22.58)	7 (25.93)	27 (30.68)	77 (25.41)	87 (22.89)
>20	7 (9.09)	0 (0.00)	6 (3.23)	9 (33.33)	7 (7.95)	22 (7.26)	29 (7.63)
Family history of diabetes	27 (39.13)	2 (100.00)	83 (53.90)	16 (66.67)	49 (61.30)	150 (57.69)	177 (53.80)
No. of people on sick leave during past three months due to diabetes	13 (35.14)	0 (0.00)	10 (10.31)	2 (14.29)	11 (20.75)	23 (13.86)	36 (17.73)
No. of days on sick leave during past three months due to diabetes	11.23 (8.20)	-	5.60 (4.20)	1.50 (0.71)	15.09 (8.03)	9.78 (8.05)	10.31 (8.02)

All variables represent n (%) other than those specified. Abbreviations: T1DM: Type 1 Diabetes Mellitus; T2DM: Type 2 Diabetes Mellitus; OGLDs: Oral Glucose Lowering Drugs; SD: standard deviation.

one-third (61/202; 30.20%) of those with T2DM had their last HbA1c below the target value as considered by the physician (**Table 4**).

Only 2.9% (10/350) participants (T1DM: 3/64 [4.69%]; T2DM: 7/286 [2.45%]) reached the global target/triple target (HbA1c < 7%, normal blood pressure [SBP/DBP: 130/80mmHg] and LDL-CS < 100 mg/dL pooled together) as per recommendations by international guidelines (**Table 4**).

Cost of medications/strips (T1DM: 42/60 [70.00%]; T2DM: 50/84 [59.52%]; Total: 92/144 [63.89%]) and lack of experience in self-managing insulin dosing (T1DM: 15/60 [25.00%]; T2DM: 31/84 [36.90%]; Total: 46/144 [31.94%]) were the main reasons for non-achievement of glycemic targets (**Table 4**).

Diabetes complications

Overall, diabetes complications were noted in 68.01% (253/372) participants, including 209/298 (70.13%) with T2DM and 44/74 (59.46%) with T1DM. The incidence of microvascular complications was higher than macrovascular complications (T2DM: 202/298 [67.79%] vs 40/298 [13.42%]; T1DM: 43/74 [58.11%] vs 2/74 [2.70%]) (**Table 4**).

Hypoglycemic episodes

Symptomatic episodes of hypoglycemia were noted in 26.01% (97/373) participants including 20.33% (61/300) with T2DM and 49.32% (36/73) with T1DM in the preceding three months. Severe hypoglycemic episodes (requiring assistance) were noted in 8.70% (32/368) participants including 5.70% (17/298) with

Table 4. Glycemic control.

	T1DM N = 77	T2DM				Total N = 304	Total N = 381
		Diet and exercise N = 2	OGLD treatment N = 187	Insulin treatment N = 27	OGLD + Insulin treatment N = 88		
People tested for HbA1c	58 (80.56)	2 (100.00)	118 (68.60)	20 (80.00)	64 (76.19)	204 (72.08)	262 (73.80)
Frequency of tests for HbA1c during past year	1.59 (1.19)	2.00 (0.00)	1.30 (0.69)	1.26 (0.73)	1.32 (0.68)	1.31 (0.69)	1.37 (0.83)
Value of last HbA1c measurement (%)	9.17 (2.19)	6.20 (0.28)	7.81 (2.35)	9.19 (2.45)	9.45 (2.55)	8.44 (2.53)	8.60 (2.48)
No. of people achieving HbA1c < 7%	6 (10.71)	2 (100.00)	48 (41.03)	4 (21.05)	12 (18.75)	66 (32.67)	72 (27.91)
Last FBG measurement (mg/dl)	145.06 (69.29)	92.65 (31.75)	136.07 (59.77)	149.94 (71.38)	145.96 (73.13)	139.82 (64.84)	140.85 (65.67)
FBG ≤ 100 mg/dL	19 (27.14)	1 (50.00)	52 (29.21)	8 (32.00)	23 (27.71)	84 (29.17)	103 (28.77)
Last PPBG measurement (mg/dl)	173.70 (79.40)	81.00 (0.00)	186.70 (85.41)	206.63 (100.25)	192.65 (111.21)	189.76 (94.86)	185.97 (91.51)
No. of people achieving global target*	3 (4.69)	0 (0.00)	6 (3.45)	0 (0.00)	1 (1.18)	7 (2.45)	10 (2.86)
People with diabetes-related complications	44 (59.46)	1 (50.00)	117 (64.29)	19 (73.08)	72 (81.82)	209 (70.13)	253 (68.01)
People with microvascular complications	43 (58.11)	1 (50.00)	112 (61.54)	18 (69.23)	71 (80.68)	202 (67.79)	245 (65.86)
People with macrovascular complications	2 (2.70)	0 (0.00)	21 (11.54)	5 (19.23)	14 (15.91)	40 (13.42)	42 (11.29)
Hypoglycemia in the preceding three months	36 (49.32)	0 (0.00)	24 (13.11)	13 (48.15)	24 (27.27)	61 (20.33)	97 (26.01)
Severe hypoglycemia in the past 12 months	15 (21.43)	0 (0.00)	6 (3.26)	4 (14.81)	7 (8.24)	17 (5.70)	32 (8.70)
Hospitalisations due to diabetes in the past 12 months	32 (42.67)	0 (0.00)	22 (12.22)	10 (40.00)	26 (29.89)	58 (19.73)	90 (24.39)

All variables represent n (%) other than those specified. *The global target is reached if HbA1c < 7% and SBP < 130 mmHg and DBP < 80 mmHg and LDL < 100 mg/dL. Number of targets reached is calculated once the 3 targets are assessable, *i.e.*, without any missing data. Percentages for “HbA1c ≥ 7%” are calculated based on non-missing data regarding “HbA1c < 7%/≥ 7%”. Abbreviations: T1DM: type 1 Diabetes Mellitus; T2DM: type 2 Diabetes Mellitus; OGLDs: oral glucose lowering drugs; SD: standard deviation; HbA1c: haemoglobin A1c; FBG: fasting blood glucose; PPBG: postprandial blood glucose.

T2DM and 21.43% (15/70) with T1DM in the preceding 12 months (**Table 4**).

Hospitalizations due to diabetes

Hospitalizations due to diabetes were reported in 24.39% (90/369) participants including 19.73% (58/294) with T2DM and 42.67% (32/75) with T1DM during the preceding 12 months (**Table 4**).

Inadequate diabetes self-care practices

Most (216/304; 71.05%) participants with T2DM had a glucometer at home. Only around one-third (44/113; 38.94%) of people with T2DM and a half (38/73; 52.05%) of those with T1DM self-managed both blood glucose and insulin; 43.86% (50/114) people with T2DM and 53.95% (41/76) people with T1DM self-adjusted insulin (**Table 5**).

Short duration of diabetes education programs

Table 5. Diabetes self-care practices.

	T1DM N = 77	T2DM				Total N = 304	Total N = 381
		Diet and Exercise N = 2	OGLD treatment N = 187	Insulin Treatment N = 27	OGLD + Insulin treatment N = 88		
No. of people screened for diabetes complications	76 (100.00)	2 (100.00)	186 (99.47)	26 (96.30)	88 (100.00)	302 (99.34)	378 (99.47)
Types of screening							
Cardiovascular disease	26 (36.62)	1 (50.00)	105 (58.01)	12 (44.44)	57 (66.28)	175 (59.12)	201 (54.77)
Eye	25 (35.21)	0 (0.00)	79 (44.38)	13 (52.00)	49 (55.68)	141 (48.12)	166 (45.60)
Nerve damage	45 (61.64)	1 (50.00)	87 (48.88)	16 (64.00)	54 (62.07)	158 (54.10)	203 (55.62)
Kidney damage (blood test for renal function)	60 (80.00)	2 (100.00)	146 (79.78)	26 (96.30)	71 (83.53)	245 (82.49)	305 (81.99)
Kidney damage (urine test for microalbumin/proteinuria)	62 (80.52)	2 (100.00)	146 (80.22)	24 (92.30)	73 (86.90)	245 (83.33)	307 (82.75)
Foot examinations	58 (77.33)	1 (50.00)	115 (63.54)	21 (77.78)	78 (89.66)	215 (72.39)	273 (73.39)
People with a glucometer at home	62 (81.58)	2 (100.00)	123 (65.78)	23 (85.19)	68 (77.27)	216 (71.05)	278 (73.16)
People that self-monitor using glucose meter	61 (98.39)	2 (100.00)	120 (97.56)	23 (100.00)	63 (92.65)	208 (96.30)	269 (96.76)
Frequency of SMBG							
n	61	2	120	23	63	208	269
Every day	37 (60.66)	1 (50.00)	38 (31.67)	10 (43.48)	18 (28.57)	67 (32.21)	104 (38.66)
Occasionally	19 (31.15)	1 (50.00)	58 (48.33)	12 (52.17)	39 (61.90)	110 (52.88)	129 (47.96)
Very occasionally	4 (6.56)	0 (0.00)	18 (15.00)	0 (0.00)	5 (7.94)	23 (11.06)	27 (10.04)
Only very occasionally	1 (1.64)	0 (0.00)	6 (5.00)	1 (4.35)	1 (1.59)	8 (3.85)	9 (3.35)
Number of SMBG tests per day	1.53 (0.67)	3.00 (0.00)	1.10 (0.39)	1.32 (0.57)	1.16 (0.43)	1.16 (0.45)	1.25 (0.53)
Timing when testing is performed*							
At all meals	1 (3.33)	0 (0.00)	2 (8.70)	0 (0.00)	1 (6.67)	3 (6.12)	4 (5.06)
At some meals (breakfast, lunch or dinner)	24 (80.00)	2 (100.00)	17 (73.91)	8 (88.89)	11 (73.33)	38 (77.55)	62 (78.48)
At bedtime	6 (20.00)	0 (0.00)	3 (13.04)	1 (11.11)	2 (13.33)	6 (12.24)	12 (15.19)
No. of people cost of strips a limiting factor for regular SMBG	49 (79.03)	0 (0.00)	60 (49.18)	15 (65.22)	39 (61.90)	114 (54.29)	163 (59.93)
No. of people who self-adjust insulin	41 (53.95)	-	-	17 (62.96)	33 (37.93)	50 (43.86)	91 (47.89)
No. of people who self-manage (both glucose and insulin)	38 (52.05)	-	0 (0.00)	15 (60.00)	29 (34.12)	44 (38.94)	82 (44.08)

Abbreviations: T1DM: type 1 Diabetes Mellitus; T2DM: type 2 Diabetes Mellitus; OGLDs: oral glucose lowering drugs; SD: standard deviation; SMBG: self monitoring of blood glucose. *A patient could have more than one test.

Most people with T1DM (69/77; 89.61%) and T2DM (283/304; 93.09%) had received diabetes education; majority (T1DM: 72/77; 93.51%; T2DM: 293/304; 96.38%) were involved in an educational program provided by the physician or his/her clinical staff. Patient education was provided by the physician in most cases; however, it lasted less than an hour in half of the instances (**Table 6**).

Table 6. Patient education.

	T1DM N = 77	T2DM				Total N = 304	Total N = 381
		Diet and exercise N = 2	OGLD Treatment N = 187	Insulin Treatment N = 27	OGLD+ Insulin Treatment N = 88		
No. of people belonging to a diabetes association or peer support group	8 (10.39)	0 (0.00)	31 (17.13)	2 (7.41)	20 (23.26)	53 (17.91)	61 (16.35)
No. of people visiting diabetes-related websites	40 (52.63)	2 (100.00)	46 (25.27)	11 (40.74)	23 (27.06)	82 (27.70)	122 (32.80)
Very often	7 (17.50)	0 (0.00)	10 (21.74)	1 (9.09)	3 (13.04)	14 (17.07)	21 (17.21)
Sometimes	22 (55.00)	2 (100.00)	26 (56.52)	7 (63.64)	13 (56.52)	48 (58.54)	70 (57.38)
Rarely	11 (27.50)	0 (0.00)	10 (21.74)	3 (27.27)	7 (30.43)	20 (24.39)	31 (25.41)
No. of people who have received diabetes education	69 (89.61)	2 (100.00)	174 (93.05)	27 (100.00)	80 (90.91)	283 (93.09)	352 (92.39)
Format of the program*							
Structured courses	13 (18.84)	0 (0.00)	26 (14.94)	1 (3.70)	19 (23.75)	46 (16.25)	59 (16.76)
Random education	45 (65.22)	2 (100.00)	114 (65.52)	25 (92.59)	54 (67.50)	195 (68.90)	240 (68.18)
Individual	46 (66.67)	1 (50.00)	118 (67.82)	18 (66.67)	55 (68.75)	192 (67.84)	238 (67.61)
In group	31 (44.93)	1 (50.00)	82 (47.13)	6 (22.22)	44 (55.00)	133 (47.00)	164 (46.59)
Unknown	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Person who delivered education[†]							
A person with diabetes	12 (17.39)	0 (0.00)	31 (17.82)	2 (7.41)	18 (22.50)	51 (18.02)	63 (17.90)
A nurse	43 (62.32)	2 (100.00)	109 (62.64)	15 (55.56)	65 (81.25)	191 (67.49)	234 (66.48)
A certified diabetes educator	11 (15.94)	0 (0.00)	24 (13.79)	2 (7.41)	9 (11.25)	35 (12.37)	46 (13.07)
A dietician or nutritionist	45 (65.22)	1 (50.00)	99 (56.90)	14 (51.85)	53 (66.25)	167 (59.01)	212 (60.23)
A physician	63 (91.30)	2 (100.00)	166 (95.40)	23 (85.19)	75 (93.75)	266 (93.99)	329 (93.47)
Other	1 (1.45)	0 (0.00)	1 (0.57)	1 (3.70)	0 (0.00)	2 (0.71)	3 (0.85)
No. of people involved in educational programs provided by the physician or his/her clinical staff	72 (93.51)	2 (100.00)	179 (95.72)	25 (92.60)	87 (98.90)	293 (96.38)	365 (95.80)
Content of the program[‡]							
Increasing knowledge on diabetes	54 (78.26)	0 (0.00)	141 (81.03)	24 (88.89)	65 (81.25)	230 (81.27)	284 (80.68)
Increasing knowledge on drugs	60 (86.96)	2 (100.00)	153 (87.93)	25 (92.59)	70 (87.50)	250 (88.34)	310 (88.07)
Increasing knowledge on diet and exercise	61 (88.41)	2 (100.00)	171 (98.28)	25 (92.59)	76 (95.00)	274 (96.82)	335 (95.17)
Providing skills (patient empowerment)	54 (78.26)	0 (0.00)	98 (56.32)	23 (85.19)	61 (76.25)	182 (64.31)	236 (67.05)
Changing attitudes and behaviour	50 (72.46)	2 (100.00)	144 (82.76)	20 (74.07)	63 (78.75)	229 (80.92)	279 (79.26)

All variables represent n (%) other than those specified. Abbreviations: T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; OGLDs: oral glucose lowering drugs. *A patient could have more than one format. [†]A patient could have more than one person who delivered education. [‡]A program could have more than one content.

4. Discussion

This international, multicenter, cross-sectional phase of IDMPs, conducted to assess the real-world management of people with T2DM and T1DM in Nigeria showed that only half of Nigerians with diabetes followed a healthy diet and exercise plan. Premix only was the most used insulin regimen, while metformin + sulfonylureas was the most used class of OGLDs. Insulin initiation was considerably delayed in people with T2DM, while, by proportion, one-third of participants had discontinued insulin. In addition to the achievement of clinical and international glycemic targets, global/triple target achievement was low. Cost of medications/strips and lack of experience in self-managing insulin were the primary reasons for non-achievement of glycemic targets. Notably, there were high incidences of diabetes complications, hypoglycemia and hospitalizations.

Dietary interventions and physical exercise remain the cornerstone of diabetes care. A healthy diet achieves optimal nutritional status and maintains good glycemic control. Likewise, regular exercise increases insulin sensitivity, improves glucose homeostasis, and reduces cardiovascular risk in diabetes [2] [22]. As unhealthy dietary habits, physical inactivity, and obesity have been identified as major risk factors in Nigerians with diabetes, diet and exercise assume added importance in diabetes management in this population [3]. However, only half the participants followed a healthy diet and exercise plan [2], which is in corroboration with several previous studies reporting poor adherence to dietary advice amongst Nigerians with diabetes [2] [23] [24].

Our study shows that in Nigeria, insulin initiation is delayed for prolonged periods ranging from five years to almost a decade. A prospective study (that enrolled consecutive people with T2DM) at the medical out-patient clinic and wards in a tertiary healthcare setting in south-East Nigeria showed that almost 84.3% participants had used insulin for less than five years [25]. International guidelines recommend early initiation of basal insulin to improve glycemic control in people with T2DM, as it offers long-term end-organ protection via “metabolic memory” regardless of subsequent treatments and degree of glycemic control [26]. Hence, it may be possible to avoid high incidence of diabetes complications as noted in our study by early insulin initiation.

In addition to delayed insulinization, most participants with T2DM in our study were receiving premixed insulin as opposed to basal insulin recommended by guidelines. Hypoglycemia was common (nearly half of the participants with T1DM and one-fifth of those with T2DM had reported symptomatic events in the preceding three months). In line with our findings, another prospective, descriptive study in Nigeria also showed that most Nigerians with T2DM were on premixed insulin and reported hypoglycemia as the most common problem [25]. Our study also noted a high incidence of hospitalizations due to diabetes, in people with both T1DM and T2DM. A meta-analysis of the United Nations demographics for Nigeria in 1990 and 2015 shows that Nigerians with T2DM are primarily hospitalized due to hyperglycemic emergencies (mainly diabetic ke-

toacidosis and hyperosmolar non-ketotic coma), diabetic foot, cardiovascular disease and stroke [8] [10]. In line with the common belief that poor glycemic control leads to diabetes complications, our study noted a sub-optimal level of glycemic control with low achievement of international, clinical and global/triple glycemic targets. Several other studies have shown sub-optimal levels of glycemic control in people with T2DM in Nigeria [4] [13] [27].

Poor self-management of diabetes in sub-Saharan Africa (including Nigeria) poses a serious threat to glycemic control [28] [29]. In our study, only around a third of people with T2DM and half of those with T1DM self-managed both blood glucose and insulin. Majority of the participants (71.1% of people with T2DM and 81.6% of those with T1DM) had a glucometer at home. However, as seen in a systematic review of studies in sub-Saharan Africa, (most studies conducted in Nigeria) most people, who have a glucometer at home, check their glucose level only once a month or irregularly, and only 1% - 2% among them measure their glucose level daily [28] [29]. Moreover, some people in Nigeria employ urine testing for monitoring glycemic control despite its limitations [2]. An audit of insulin prescription patterns and associated burden among people with diabetes in a tertiary health institution showed that Nigerians who self-injected insulin showed better adherence than those being injected by health care professionals or relations [30]. In line with this study, where more than a quarter (27.2%) of people with diabetes reported non-adherence (or skipping insulin injections), in our study almost one-third of people with T2DM discontinued insulin. As non-adherence is a major factor that could lead to poor glycemic control, increased morbidity and mortality, promoting adherence to insulin can help people manage their diabetes better [31].

Diabetes Self-Management Education (DSME) plays a critical role in increasing adherence to insulin, promoting adoption of self-management behaviors, and creating disease awareness by addressing traditional perceptions and cultural beliefs that fuel misconceptions [16] [28]. A retrospective study that included people with T2DM in Alimosho General Hospital, Igando, Lagos, Nigeria revealed widespread ignorance regarding diabetes among people (19.7% people believed T2DM could be cured permanently, 2.0% believed they could personally control their blood glucose level without using drugs while 14.5% had no idea about the disease) [31], indicating an urgent need for patient education programs. Our study shows that though most people with diabetes receive diabetes education, and it is provided by the physician in most cases, it lasts less than an hour in half of the instances. In view of high ignorance levels amongst Nigerians with T2DM (evident from aforementioned studies), the duration of patient education programs may be deemed fairly inadequate. As inadequate diabetes knowledge has been identified as a significant determinant of poor glycemic control, promotion of patient education initiatives can go a long way in optimizing glycemic control and long-term disease outcomes in Nigeria [27].

This multicenter, cross-sectional study provides crucial insights into the

real-world management of diabetes in Nigeria. In view of limited data on diabetes care in this region, our study provides vital data on the existing diabetes care landscape in this region, highlights gaps and indicates the areas of improvement. However, as the study could not reach the required sample size (396 participants were required, while only 381 were included), the results might need to be interpreted with caution. The observational study design was prone to inherent shortcomings such as bias, confounding factors, etc. Moreover, the cross-sectional study design prevented long-term follow-up to ascertain the influence of patient education initiatives. Despite the observation of sub-optimal level of glycemic control in this region, the study failed to explore the impact of existing healthcare interventions, which could have helped determine the framework of future studies and resource allocation efforts.

5. Conclusion

This real-world study on diabetes management practices in Nigeria reveals a sub-optimal level of glycemic control, suggested by low achievement of glycemic targets and high incidence of diabetes complications. Our study highlights several gaps including delayed insulin initiation, early discontinuation, unaffordability of test strips and lack of experience in self-management with insulin in the real-world setting. In view of these challenges, there may be a need for early insulin initiation strategy in Nigerian people with T2DM. Subsidization of diabetes test strips, and targeted patient education campaigns to promote self-management of blood glucose and insulin can be crucial in elevating the level of diabetes care in Nigeria.

Declarations

Funding

This study was funded by Sanofi.

Availability of Data and Material

Qualified researchers may request access to person - level data and related study documents including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan, and dataset specifications. Person-level data will be anonymized, and study documents will be redacted to protect the privacy of trial participants. Further details on Sanofi's data sharing criteria, eligible studies, and the process for requesting access can be found at <https://www.clinicalstudydatarequest.com>.

Authors' Contributions

KBA was involved with the conception and design of the study, acquisition, and interpretation of data, drafting of the manuscript and approved the final manuscript.

AFA contributed to the conception of the study, data acquisition, critical review of the manuscript and approval of the final draft.

UC participated in the design of the study, data acquisition, and preparation of the manuscript.

Ethics Approval

The study was conducted in accordance with the Declaration of Helsinki, the principles laid by the 18th World Medical Assembly (Helsinki, 1964) [21] and all subsequent amendments. It is aligned with the guidelines for Good Epidemiology Practice (US & European). It was approved by ethics committee of Nigeria and participating centers and was performed in accordance with local regulations, including local data protection regulations. Study design and reporting format followed the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. All participants provided signed informed consent before study participation and data collection/documentation.

Consent to Participate

All patients signed a written informed consent prior to the study conduct.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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